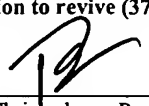


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|---|--|---|--|--|--|
| FORM PTO-1390<br>(REV. 12-2004)   |  | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE |  | ATTORNEY'S DOCKET NUMBER   |  |
| <b>TRANSMITTAL LETTER TO THE UNITED STATES<br/>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br/>CONCERNING A FILING UNDER 35 U.S.C. 371</b>   |  |   |  | TAN-05-1079  |  |
|   |  |   |  | U.S. APPLICATION NO. (If filing under 37 C.F.R. 1.5)<br><b>10/530664</b> |  |
| INTERNATIONAL APPLICATION NO.<br>PCT/JP2003/012890  |  | INTERNATIONAL FILING DATE<br>08 October 2003 (08.10.03) |  | PRIORITY DATE CLAIMED<br>09 October 2002 (09.10.02)                      |  |
| TITLE OF INVENTION<br><b>REMEDIES OR PREVENTIVES FOR URINARY FREQUENCY OR URINARY INCONTINENCE AND MORPHINAN<br/>DERIVATIVES HAVING NITROGEN-CONTAINING HETEROCYCLIC GROUP</b>  |  |   |  |  |  |
| APPLICANT(S) FOR DO/EO/US<br>Naoki Izumimoto, Koji Kawai, Kuniaki Kawamura, Morihiro Fujimura and Toshikazu Komagata  |  |   |  |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |  |   |  |  |  |
| 1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.<br>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.<br>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.<br>4. <input type="checkbox"/> The US has been elected (Article 31).<br>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))<br>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).<br>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.<br>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).<br>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))<br>a. <input checked="" type="checkbox"/> is attached hereto.<br>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).<br>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))<br>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).<br>b. <input type="checkbox"/> have been communicated by the International Bureau.<br>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.<br>d. <input checked="" type="checkbox"/> have not been made and will not be made.<br>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).<br>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).<br>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).<br><br><b>Items 11 to 20 below concern document(s) or information included:</b><br>11. <input type="checkbox"/> An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98.<br>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.<br>13. <input checked="" type="checkbox"/> A preliminary amendment.<br>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 C.F.R. 1.76.<br>15. <input type="checkbox"/> A substitute specification.<br>16. <input type="checkbox"/> A power of attorney and/or change of address letter.<br>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 C.F.R. 1.821 - 1.825.<br>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).<br>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).<br>20. <input type="checkbox"/> Other items or information: |  |   |  |  |  |

|  |              |   |              |   |           |
|--|--------------|---|--------------|---|-----------|
| U.S. APPLICATION NO. (If known, see 37 CFR 1.5)<br><b>107530664</b>  |              | INTERNATIONAL APPLICATION NO.<br>PCT/JP2003/012890                            |              | ATTORNEY'S DOCKET NUMBER<br>TAN-05-1079 |           |
| 21. The following fees are submitted:  |              |   |              |   |           |
| <input checked="" type="checkbox"/> a) Basic national fee.....   |              |   |              | \$ 300.00                               |           |
| <input checked="" type="checkbox"/> b) Examination fee.....  |              |   |              | \$ 200.00                               |           |
| <input checked="" type="checkbox"/> c) Search fee.....   |              |   |              | \$ 500.00                               |           |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>   |              |   |              | <b>\$1,000.00</b>                       |           |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250.00 for each additional 50 sheets of paper or fraction thereof.  |              |   |              |   |           |
| Total Sheets   | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | Rate         |   |           |
| 212 - 100 =  | 112/50 =     | 3   | x \$250.00   | \$ 750.00                               |           |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).   |              |   |              | \$ 130.00                               |           |
| CLAIMS   |              | NUMBER FILED  | NUMBER EXTRA | RATE                                    |           |
| Total Claims   |              | 22 - 20 =   | 2            | x \$50.00                               | \$ 100.00 |
| Independent claims   |              | 2 - 3 =   | 0            | x \$200.00                              | \$        |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)  |              |   | + \$360.00   | \$                                      |           |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>   |              |   |              | <b>\$1,980.00</b>                       |           |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.   |              |   |              | \$                                      |           |
| <b>SUBTOTAL =</b>  |              |   |              | <b>\$1,980.00</b>                       |           |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).  |              |   |              | \$                                      |           |
| <b>TOTAL NATIONAL FEE =</b>  |              |   |              | <b>\$1,980.00</b>                       |           |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property   |              |   |              | +                                       | \$        |
| <b>TOTAL FEES ENCLOSED =</b>   |              |   |              | <b>\$1,980.00</b>                       |           |
|  |              |   |              | Amount to be refunded:                  | \$        |
|  |              |   |              | Amount to be charged:                   | \$        |
| a. <input checked="" type="checkbox"/> A check in the amount of \$1,980.00 to cover the above fees is enclosed.<br>b. <input type="checkbox"/> Please charge my Deposit Account No. 50-2719 in the amount of \$_____ to cover the above fees.<br>A duplicate copy of this sheet is enclosed.<br>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2719. A duplicate copy of this sheet is enclosed.<br>d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038. |              |   |              |   |           |
| <b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.   |              |   |              |   |           |
| <b>SEND ALL CORRESPONDENCE TO:</b><br><br><b>Customer No. 035811, whose contact information is:</b><br><b>IP Group of DLA Piper Rudnick Gray Cary US LLP</b><br><b>One Liberty Place, Suite 4900</b><br><b>1650 Market Street</b><br><b>Philadelphia, PA 19103</b><br><b>(215) 656-3381</b>  |              |   |              |   |           |

  
T. Daniel Christenbury, Reg. No. 31,750

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : Customer No.: 035811  
Examiner :  
Serial No. :  
Filed : Herewith  
PCT No. : PCT/JP2003/012890  
PCT Filed : October 8, 2003  
Inventors : Naoki Izumimoto Docket No.: TAN-05-1079  
: Koji Kawai Confirmation No.:  
: Kuniaki Kawamura  
: Morihiro Fujimura  
: Toshikazu Komagata  
Title : REMEDIES OR PREVENTIVES FOR  
: URINARY FREQUENCY OR URINARY  
: INCONTINENCE AND MORPHINAN  
: DERIVATIVES HAVING NITROGEN-  
: CONTAINING HETEROCYCLIC GROUP

Dated: April 6, 2005

**APPLICATION TRANSMITTAL LETTER**

**MAIL STOP PCT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

We submit herewith for filing in the U.S. Patent and Trademark Office a Certificate of Verification, an English translation of the above-identified PCT Application as filed including 203 pages of Specification, 8 pages of Claims and 1 page Abstract, Application Data Sheet (2 pages), a Preliminary Amendment, copies of the Request (5 pages), Form PCT/IB/308, the first page of WO 2004/033457 A1, Form PTO-1390, in duplicate, and our check in the amount of \$1,980.00, comprising the official filing fee.

Respectfully submitted,



T. Daniel Christenbury  
Reg. No. 31,750  
Attorney for Applicants

TDC:lh  
(215) 656-3381

Rec'd PTO 09 JUN 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1614 Customer No.: 035811  
Examiner :  
Serial No. : 10/530,664  
Filed : April 6, 2005  
Inventors : Naoki Izumimoto Docket No.: TAN-05-1079  
: Koji Kawai Confirmation No.: 7651  
: Kuniaki Kawamura  
: Morihiro Fujimura  
: Toshikazu Komagata  
Title : REMEDIES OR PREVENTIVES FOR  
: URINARY FREQUENCY OR URINARY  
: INCONTINENCE AND MORPHINAN  
: DERIVATIVES HAVING NITROGEN-  
: CONTAINING HETEROCYCLIC GROUP

Dated: June 9, 2005

**TRANSMITTAL LETTER**

**Mail Stop PCT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

We submit herewith the original, executed Combined Declaration, Power of Attorney and Petition and request that it be formally entered in the file of the case.

The surcharge for filing the Combined Declaration later than the date of actual filing of the application in the U.S. Patent & Trademark Office was paid when the application was filed as indicated on Form PTO-1390.

The Commissioner is authorized to charge any insufficiency or credit any overpayment to Deposit Account No. 50-2719. This authorization is made in duplicate.

Respectfully submitted,



T. Daniel Christenbury  
Reg. No. 31,750

TDC:vbm  
(215)656-3381

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit :  
Examiner :  
Serial No. :  
Filed : Herewith  
PCT No. : PCT/JP2003/012890  
PCT Filed : October 8, 2003  
Inventors : Naoki Izumimoto  
: Koji Kawai  
: Kuniaki Kawamura  
: Morihiro Fujimura  
: Toshikazu Komagata  
Title : REMEDIES OR PREVENTIVES FOR  
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: DERIVATIVES HAVING NITROGEN-  
: CONTAINING HETEROCYCLIC GROUP

Customer No.: 035811  
Docket No.: TAN-05-1079  
Confirmation No.:

Dated: April 6, 2005

**MAIL STOP PCT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**37 CFR 1.10  
EXPRESS MAIL CERTIFICATION**

"Express Mail" mailing label number: EV 548523610 US

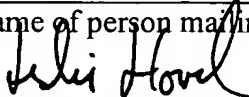
Date of Deposit: April 6, 2005

DESCRIPTION OF CONTENTS: Postcard, \$1,980.00 Check, Application Transmittal Letter, in duplicate, Form PTO-1390, in duplicate, Certificate of Verification, English translation of PCT Application as filed, including 203 pages of Specification, 8 pages of Claims and 1 page Abstract, Application Data Sheet (2 pages), Preliminary Amendment, copies of Request (5 pages), Form PCT/IB/308, and first page of WO 2004/033457 A1.

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to **Mail Stop PCT**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Leslie Hood

(Typed or printed name of person mailing paper or fee)



(Signature of person mailing paper or fee)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1614 Customer No.: 035811  
Examiner :  
Serial No. : 10/530,664  
Filed : April 6, 2005  
Inventors : Naoki Izumimoto Docket No.: TAN-05-1079  
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Title : REMEDIES OR PREVENTIVES FOR  
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: INCONTINENCE AND MORPHINAN  
: DERIVATIVES HAVING NITROGEN-  
: CONTAINING HETEROCYCLIC GROUP

Dated: June 9, 2005

**Mail Stop PCT**

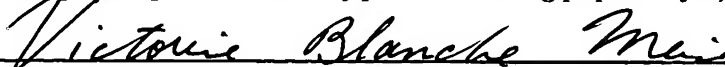
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**EXPRESS MAIL CERTIFICATION****37 C.F.R. §1.10**

Express Mail Label No.: EV 548522486 US  
Date of Deposit: June 9, 2005  
Description of Contents: Postcard, Transmittal Letter, in duplicate, original, executed Combined Declaration, Power of Attorney and Petition, Information Disclosure Statement, Form PTO-1449 and copy of International Search Report mailed 11/25/03 with English Translation.

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR§1.10 on the date indicated above and is addressed to **Mail Stop PCT**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Victorine Blanche Meise

*(Typed or printed name of person mailing paper or fee)**(Signature of person mailing paper or fee)*